# fontem ventures

**December 2015**

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# Fontem Ventures: Meeting with OIRA

- Fontem Ventures is dedicated to developing and growing a portfolio of innovative products including Electronic Vaping Products (EVPs). A subsidiary of Imperial Tobacco Group (ITG), we nevertheless operate at arm's length from our parent company and are focusing on non-tobacco opportunities only.

- We are committed to developing and manufacturing high-quality EVPs, and to utilize best practices in quality control and product stewardship to do so. Accordingly, Fontem has implemented a product stewardship program that focuses on assessment of materials, product performance testing, and a responsible and informed choice of suppliers and ingredients. It has also adopted voluntary controls for product advertising which are aimed exclusively at adult consumers.

- Fontem believes that these practices result in high-quality products that could potentially provide a public health benefit. We therefore support adoption of an evidence-based regulatory framework for EVPs that takes proper account of the differences between EVPs and tobacco products. EVPs are fundamentally different from tobacco products and a clear regulatory separation is necessary.

- There is a fast emerging scientific consensus that EVPs are considerably less harmful than tobacco products and that every consumer of tobacco products that switches to EVPs is a net gain in public health terms (for the most up to date overview see Public Health England, 2015).

- What is therefore needed is regulation that sets the parameters and incentives for the development of an EVP market characterized by strong innovation, high-quality products, and reliable information and high transparency to educate consumers. The ideal policy outcome from a public health perspective is a complete switch of all consumers of tobacco products to EVP, without attracting non-smokers and minors to the category.

- The currently foreseen regulatory framework fails to set these parameters and incentives in crucial aspects and thus misses a chance to achieve an overall better public health outcome.

- **Pre-market authorization and innovation:** A balance needs to be struck between the need to innovate and administrative oversight of new products. Pre-market authorization needs to have the explicit aim of allowing innovative products onto the market as soon as possible to achieve better public health outcomes. This means most importantly that existing products should not be required to undergo an authorization procedure.

    - If the 2007 grandfather date remains in place then Pre-market tobacco authorization (PMTA) will be required for all brands of EVP on the U.S. market, which would impose disproportionate burdens on consumers thereby reducing better public health outcomes. As such, we would need to legally challenge such a provision to safeguard our legitimate business interests and consumer health benefits.

- **Ensuring necessary "attractiveness" of EVPs:** The concept of "attractive" EVPs is difficult to approach from a legal perspective, but becomes ultimately important from a public health perspective. Since every tobacco consumer switching to EVPs is a net gain from a public health perspective, they need incentives to do so. Nicotine and flavors, which are clearly not intended for minors, play an instrumental role in creating category attractiveness, and this should be reflected in the final regulations.

SMARTT
COALITION

August 8, 2014

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0189: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Products and Required Warning Statements for Tobacco Products

Dear Sir or Madam:

The Small Manufacturers Association for the Reasonable Treatment of Tobacco ("SMARTT") submits the following comments in response to the proposed regulation provided in the above-referenced docket (the "Deeming Regulation" or "Proposed Rule") deeming products meeting the statutory definition of "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act"). SMARTT is a coalition of Subsequent Participating Manufacturers to the multi-state Master Settlement Agreement who share issues of common concern with respect to the implementation of the Tobacco Control Act. We appreciate this opportunity to comment on the Proposed Rule as part of our ongoing efforts to assist the U.S. Food and Drug Administration's ("FDA's" or the "Agency's") Center for Tobacco Products ("CTP") in the effective and efficient implementation of the Act.

With respect to the Proposed Rule, FDA solicits comments and information on a wide variety of topics, including, among others: (i) comment on the overall proposed rule; (ii) whether and, if so, how FDA should consider a different regulatory mechanism for newer proposed deemed tobacco products that cannot, as a practical matter use the Substantial Equivalence ("SE") pathway; (iii) whether it might be appropriate for the protection of the public health to stagger the compliance dates for certain provisions for different categories of products; and (iv) comments on the estimates and methodology used to estimate the information collection burden associated with premarket review.[1]

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[1] 79 Fed. Reg. 23142, 23144-45 and 23189 (Apr. 25, 2014).

SMARTT acknowledges the challenges associated with extending the provisions of the Tobacco Control Act, and the premarket review provisions in particular, to additional categories of tobacco products that differ greatly in their technology, ingredients, and methods of manufacture. We believe many of these challenges can be traced to decisions reached by FDA when it first implemented the premarket review provisions several years ago. At that time, SMARTT submitted public comments to FDA urging the Agency to adopt a framework for premarket review of "new tobacco products" that, like the statutory language of "substantial equivalence," is based on the longstanding statutory and regulatory framework for the premarket review of medical devices. We believe that had FDA adopted the recommendations provided in our comment letter, the Agency could have avoided the significant burdens on both FDA and industry that have resulted from CTP's since-implemented approach to premarket review.

In this comment letter, we detail the reasons why FDA should revisit the premarket review provisions in the Proposed Rule if the Agency is to achieve its objectives of conserving resources and minimizing industry disruption in a manner that is appropriately protective of the public health. We also detail a model of premarket review that is legally permissible under the text of the Act and that would better serve these ends. Moreover, SMARTT's proposal would provide a platform on which FDA could promulgate and implement tobacco category-specific guidance in connection with several other provisions of the Act, such as current good manufacturing practice requirements and tobacco product standards. Specifically, the comments make the following points:

- FDA's narrow interpretation of the Tobacco Control Act's premarket review provisions as applied to currently-regulated tobacco products resulted in a one-size-fits-all approach to regulation untethered from the public health goals of the Act, which has tremendously burdened FDA resources while also resulting in significant industry disruption;

- Application of the premarket review provisions to newly-deemed tobacco products as outlined in the Proposed Rule will only make matters worse, and is unnecessary as a matter of law and as a means to achieve the public health goals of the Act.

- The text of the Tobacco Control Act provides FDA with the inherent authority to adopt different models of regulation, including in the premarket review context, that are tailored to the category of tobacco product at issue and FDA's assessment of the relative risks posed by that product.

    - The definition of substantial equivalence permits review and approval of products with "different characteristics" that do not raise different questions of public health, thus providing FDA with flexibility to review tobacco products with no clear pre-2007 versions against other, verified predicate tobacco products.

    - Similarly, with respect to premarket tobacco product applications ("PMTAs"), the statute makes clear that clinical studies are

required only "when appropriate" and permits approval on the basis of other "valid scientific evidence," thus providing FDA with flexibility in promulgating category-specific requirements and standards for approval.

- The challenges associated with regulating tobacco products are obviously similar to the challenges of regulating medical devices, which represent a wide variety of technologies and risks. Indeed, the *de novo* classification process for medical devices was established to address much the same problem currently confronting CTP—namely, the waste of industry and FDA resources associated with "full" PMA review of relatively low-risk medical products. SMARTT believes that the *de novo* process provides a clear model for regulation of tobacco products, but that, unlike the *de novo* process, which required Congressional intervention to address inefficiencies in the device premarket review process, CTP possesses the authority today under the Tobacco Control Act to promulgate and implement a similar framework for tobacco products.

- Both in response to this docket, and upon the effective date of the Deeming Regulation, FDA will receive a significant amount of information regarding the newly-deemed tobacco products, including data regarding the health risks of the products, their ingredients and constituents, and the users of the products. This information should be used to facilitate the development of tobacco category-specific guidance prior to the date on which industry must file premarket reports, thus providing transparency to industry on the requirements and criteria that will be applied by FDA during premarket review—transparency industry has lacked to date. Put another way, FDA need not wait to receive premarket submissions (which are likely to number in the thousands) and then establish the standards for review and approval during the pendency of review.

- The Proposed Rule provides FDA with an opportunity to revisit its current approach to premarket review and establish a regulatory framework that will stand the test of time and better serve the public health objectives of the Tobacco Control Act. In contrast, if FDA fails to alter its current course, the Agency is likely to receive thousands of premarket filings that must be reviewed individually, thus exacerbating (rather than resolving) the problems that currently beset FDA's premarket review regime.

In sum, we believe that the recommendations contained in this letter will allow FDA to develop and implement a premarket review program (and approach to regulation more generally) that is more transparent in its requirements, more reflective of the resources CTP will be able to bring to bear in regulating newly-deemed products, and, ultimately, a better means for achieving the public health goals of the Tobacco Control Act.

## I. THE DEEMING REGULATION SHOULD REFLECT THE DISTINCTIONS BETWEEN AND WITHIN CATEGORIES OF TOBACCO PRODUCTS

The FDCA, as amended by the Tobacco Control Act, authorized FDA to regulate the manufacture, marketing, and distribution of tobacco products in order to protect the public health and reduce tobacco use by minors.[2] The statute vested FDA with immediate authority to regulate four classes of tobacco products (namely, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco), and further authorized the Agency to regulate other tobacco products by "deeming" them subject to the Act in a subsequent rulemaking.[3] In April 2014, FDA issued the Proposed Rule, which sets forth two potential approaches to making currently unregulated products subject to the Act[4]:

- *Option 1:* Would extend FDA's "tobacco product" authorities to all other categories of products, except accessories of a proposed deemed tobacco product, that meet the statutory definition of "tobacco product" in the FDCA.

- *Option 2:* Would extend FDA's "tobacco product" authorities to all other categories of products, except "premium cigars" (as therein defined) and the accessories of a proposed deemed tobacco product, that meet the statutory definition of "tobacco product" in the FDCA.

According to FDA, Option 2 was developed in response to data and information establishing that different types of cigars have differing public health profiles.[5] Likewise, this approach dovetails with FDA's more general statement that there are distinctions in the hazards presented by various nicotine-containing products. For that reason, SMARTT is supportive of the adoption of Option 2 for the reasons articulated in comment letters submitted by the Cigar Association of America; Nat Sherman International, Inc.; and Altadis U.S.A., Inc., Premium Cigar Division, respectively. That said, we strongly urge FDA to extend the Agency's cigar-specific assessment to other categories of tobacco products, which, as a rule, also contain a wide degree of inter-category and intra-category variations that render one-size-fits-all regulation inappropriate. In other words, FDA's overarching approach to the Deeming Regulation should reflect the Agency's position that there are distinctions in the hazards presented by nicotine-delivering products.[6] Toward that end, in these comments, SMARTT proposes an alternative regulatory approach—an "Option 3", so to speak—which would permit FDA to account for the differences among deemed tobacco products and implement the regulatory controls of the Act in light thereof.

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2 *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 3(2), 123 Stat. 1776, 1784 (2009) (hereinafter, "Tobacco Control Act")..

3 FDCA § 901(b); 21 U.S.C. at § 387a(b).

4 79 Fed. Reg. at 23143.

5 *Id.*

6 *Id.* at 23147.

In short, SMARTT's proposal facilitates the promulgation and implementation of product-class specific regulation tailored to the tobacco products at issue across several areas, including premarket review requirements, tobacco product standards, advertising and promotional requirements, and good manufacturing practices. Utilizing enforcement discretion[7] and guidance, as it has routinely done in implementing the Tobacco Control Act to date, FDA could establish a medical device-like framework that allows CTP to allocate its resources by tobacco product classification. Specifically, these comments call for the application of the Tobacco Control Act's "general controls" to all covered deemed tobacco products,[8] while developing and establishing additional, product category-specific "special controls" in the form of guidance to industry. This recommended approach would create a scientifically sound and workable regulatory system for heterogeneous tobacco products, thereby giving effect to the Tobacco Control Act's mandate that the regulation of each tobacco product category be *appropriate* (that is, suitable or proper *in the circumstances*)[9] for the protection of public health.

## II. FAILURE TO ACKNOWLEDGE THE DISTINCTIONS AMONG TOBACCO PRODUCTS FRUSTRATES THE PURPOSES OF THE TOBACCO CONTROL ACT

### A. FDA's Current Approach to Premarket Review Frustrates the Purposes of the Act

The Tobacco Control Act was enacted to establish a regulatory framework that addresses the public health and societal problems attributable to tobacco. The legislation was intended to achieve certain statutorily enumerated purposes, including among others: (i) to ensure that FDA "has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;"[10] (ii) to provide the Agency with "new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;"[11] (iii) to continue to "permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage

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7 The Proposed Rule is replete with FDA's acknowledgement of the enforcement discretion the Agency may exercise in implementing the provisions of the Tobacco Control Act. For example, in proposing Option 2, FDA signals a willingness to use its discretion and decline to extend the premarket review and other requirements for tobacco products to those products which meet the definition of "premium cigars." Similarly, the fact that FDA is soliciting comments about how e-cigarettes and other products should be regulated serves as an implicit recognition of the "flexible enforcement authority" which has been granted to the Agency. Indeed, such an exercise of enforcement discretion follows from the Obama Administration's mandate that FDA "identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public." *See* Exec. Order No. 13,563, 76 Fed. Reg. 3,821 (Jan. 21, 2011).

8 As currently proposed, "covered tobacco products" are those tobacco products that are deemed to be subject to the FDCA, excluding any components or parts that do not contain tobacco or nicotine. 79 Fed. Reg. at 23204.

9 Oxford English Dictionary.

10 Tobacco Control Act § 3(2).

11 *Id.* § 3(4).

purchasers;"[12] and (iv) to impose "appropriate regulatory controls on the tobacco industry."[13] Achieving these purposes should be the starting point of FDA's regulatory mission in asserting jurisdiction over currently unregulated tobacco products, and should guide FDA in each implementation activity contemplated under the Act.

FDA expresses its intent to fulfill these statutory purposes in the preamble to the Proposed Rule, where the Agency states as follows:

> Implementation of these proposed provisions would allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market. The proposed provisions would also provide a mechanism through which those products that are less harmful or addictive could enter the market. The greater regulatory certainty created by premarket authorizations should help companies to invest in creating novel products, with greater confidence that improved products will enter the market without having to compete against equally novel, but more dangerous products....Over time, the employment of the premarket authorities can spur innovation and help to create a market where available products are less dangerous when consumed, less likely to lead to initiation of tobacco use, and/or easier to quit.[14]

Although SMARTT appreciates the optimism expressed in these commendable goals, we believe that FDA's implementation of the Tobacco Control Act to date suggests that the language above is purely aspirational, and that FDA's objectives will not be met without a fundamental change in the Agency's approach to tobacco regulation.

FDA's ongoing efforts to implement the Tobacco Control Act underscore the inherent difficulty that CTP faces in fulfilling these statutory purposes through one-size-fits-all regulation. Consider, for example, CTP's experience to date in applying premarket review requirements in a uniform manner to all currently regulated classes of tobacco products. The Tobacco Control Act requires that all "new tobacco products" be submitted to FDA for premarket review and approval prior to commercialization in the United States.[15] The FDCA, as amended, outlines three distinct premarket review pathways for tobacco products, including submission of a report under FDCA Section 910 (Premarket Tobacco Product Application or "PMTA"),[16] a report under FDCA Section 905(j) ("Substantial Equivalence Report" or "SE Report"),[17] or in lieu of the latter, a request for exemption from substantial equivalence

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12 *Id.* § 3(7).

13 *Id.* § 3(8).

14 79 Fed. Reg. at 23149.

15 *See* FDCA § 910(a); 21 U.S.C. § 387j(a).

16 *See* FDCA § 910(b); 21 U.S.C. § 387j(b).

17 *See* FDCA § 905(j); 21 U.S.C. § 387e(j).

requirements under FDCA Section 905(j)(3) ("SE Exemption Requests").[18] To date, all three of these pathways have been plagued by significant regulatory uncertainty, and none of them has proved to be a viable route for products of any class to enter the market in the more than five (5) years since the passage of the Tobacco Control Act. Rather than spurring new products and innovation, FDA's interpretation of the premarket review portions of the Tobacco Control Act has essentially frozen the industry. The numbers speak for themselves:

- *PMTAs.* Of the four (4) total PMTA submissions that industry has made to date, not a single one (0) has been accepted for filing by CTP.[19]

- *SE Exemption Requests.* Of the 59 SE Exemption requests reportedly submitted to date, at least 36 (or 61%) of these requests received Refuse-to-Accept (RFA) letters from the Agency. It is unclear how many of the remaining requests, if any, have ever been granted.[20]

- *MRTPAs.* Although not technically an independent premarket review pathway, it is worth noting that none (0) of the five (5) Modified Risk Tobacco Product applications ("MRTPAs") submitted pursuant to FDCA Section 911 were deemed complete and appropriate for the Agency's review. Accordingly, no MRTPs, which are defined as products sold or distributed for use to reduce the harm or risk of tobacco-related disease, have been substantively reviewed by FDA, let alone commercially marketed since the passage of the Act.[21]

- *SE Reports.* The SE pathway is most emblematic of the inherent problems with FDA's current approach to premarket review. Of the 4,400+ SE Reports submitted for currently regulated products (more than 3,500 of which were submitted by industry on or before the statutory grace period deadline of March 22, 2011),[22] only 88 such submissions have received final orders on the merits to date.[23] In other words, FDA has issued final orders granting or denying substantial equivalence for *fewer than 2%* of total SE submissions received since November 2010, and most petitions have been pending without any decision from the Agency for up to *12 times* the abbreviated 90-day statutory period Congress specified in the Act. Moreover, FDA reports that nearly all industry SE submissions have generated one or more

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18 *See* FDCA § 905(j)(3); 21 U.S.C. § 387e(j)(3).

19 *See* FDA, Tobacco Product Marketing Orders, *available at* http://www.fda.gov/tobaccoproducts/labeling/marketingandadvertising/ucm339928.htm (last accessed August 1, 2014).

20 *Id.*

21 FDA, FDA-TRACK CTP Office of Science Dashboard, Total number of product submissions received or filed in the month, available at http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all (last accessed July 20, 2014).

22 *Id.*

23 *See* http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm (last accessed August 1, 2014).

Advice/Information Request Letters from CTP,[24] meaning that nearly 4,400 *additional* sets of data and information have also been collected as part of the Agency's current SE review process.

Given the sheer volume of SE submissions received by FDA to date, it comes as no surprise that the Agency has spent much of its limited resources attempting to manage this process. Yet notwithstanding the fact that the FDCA does not permit the Agency to ban tobacco products, FDA's current approach to premarket review (and SE review, in particular) freezes the status quo and acts as a *de facto* ban on new products, including any innovative or improved products.[25] SMARTT attributes these dramatic and systemic flaws in the current SE review process to four distinct issues, namely: (i) an underestimation by FDA of the annual number of SE filings to be submitted to the Agency; (ii) a willingness to regulate in the absence of the necessary data to develop science-based requirements; (iii) an expansive interpretation of the SE provisions which does not further the public health goals of the Act; and (iv) implementation of a one-size-fits-all approach to premarket review which fails to acknowledge and account for the tremendous diversity among and within tobacco product classes.[26]

As a baseline matter, FDA grossly underestimated the total number of premarket review filings that the Agency would receive each year for currently regulated products. In January 2011, the Agency estimated that 150 firms would each submit one (1) SE Report or PMTA per year, such that FDA would review only 150 premarket submissions in a given year.[27] However, as noted above, firms have submitted more than 4,400 SE Reports and 4 PMTAs in a 3.5 year period. This averages to more than 1,200 submissions per year, *or eight times* FDA's initial estimate. In hindsight, it is clear that the Agency was ill-equipped to handle such a heavy volume of submissions, particularly where several thousands of submissions spanning multiple product classes came flooding in to FDA at the same time.

In addition to underestimating the submissions to be received, FDA erred in establishing the deadline by which those submissions had to be made. CTP could have exercised its enforcement discretion and not required industry to submit SE Reports until the Agency had determined the kind of information that should be included in such submissions. Instead, FDA issued a guidance document on January 5, 2011—a mere 11 weeks before the statutory deadline

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24 CTP, Webinar: Common Issues Identified During FDA's Scientific Evaluation of Substantial Equivalence Reports (Aug. 21, 2012) (hereinafter, "CTP Webinar").

25 SMARTT believes that this *de facto* ban is a clear violation of the Act, as Congress has explicitly prohibited FDA from banning "all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products" or "requiring the reduction of nicotine yields of a tobacco product to zero." FDCA § 907(d)(3); 21 U.S.C. § 387g(d)(3).

26 SMARTT submitted multiple comments when FDA first implemented the SE review process that identified these flaws and correctly predicted the outcome that FDA is struggling with today. *See, e.g.*, Commonwealth Brands, JT International U.S.A., King Maker Marketing, Nat Sherman, and Swedish Match Comment, FDA-2010-D-0635-0009 (noting that "a broad interpretation of the Section 905(j) reporting mandate – as manifested in the SE Guidance – will impose an incredible and unnecessary administrative burden on the Agency and the tobacco product manufacturing industry.")

27 76 Fed. Reg. 4116 (Jan. 24, 2011).

of March 22, 2011.[28] It was only after receiving the more than 3,500 SE submissions that FDA realized that its guidance document had failed to communicate all the information CTP believed it needed to make SE determinations. FDA hosted a webinar in August 2012 to address this issue and, in violation of FDA Good Guidance Practices,[29] introduced a number of wholly new submission requirements.[30] In retrospect, it is clear that a premature submission deadline which was divorced from a solid grounding in regulatory science contributed to an inefficient, ever-changing, and unnecessarily burdensome review process which wasted an untold amount of industry and Agency resources—a problem that continues today with respect to currently regulated tobacco products.

FDA's current approach to premarket review is further complicated by Agency guidance documents which (i) evidence an overly broad interpretation of SE requirements and mandate a host of unnecessary SE filings and (ii) fail to account for the practical realities of manufacturing with an agricultural product such as tobacco. The existing regulatory framework effectively requires that any change to a tobacco product's ingredients or additives be reported to FDA in an SE Report, regardless of the nature, intent, or permanency of the change. All of these considerations should be key factors in determining whether a change implicates questions of public health such that it requires FDA premarket review. Moreover, narrowly applying these factors to tobacco products is impractical if not impossible in light of the regional, climatic, and agricultural variability in tobacco crops.[31] Finally, FDA's overly narrow interpretation of the statutory definition of substantial equivalence means that any change to a tobacco product, irrespective of how minor, is considered to automatically raise "different questions of public health." Thus, FDA's current implementation of the SE process has resulted in a deluge of premarket review submissions, many of which are for inconsequential and/or minor (from the public health perspective) changes that Congress never intended be subject to the SE process in the first place.

Finally, FDA's one-size-fits-all approach to premarket review has created a monolithic review system which fails to recognize or account for the heterogeneity of the tobacco industry. This regulatory approach stands in direct opposition to FDA's express position that there are distinctions in the hazards presented by various types of tobacco products, and the Tobacco Control Act's goal of preventing youth access to tobacco products. Congress clearly

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28 *See* FDA, Guidance for Industry: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products (Jan. 2011), available at http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf.

29 *See* 21 C.F.R. § 10.115(e) (noting that FDA "may not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time").

30 CTP Webinar.

31 SMARTT emphasizes that these factors may be particularly acute with respect to the tobacco products subject to the Deeming Regulation, many of which (e.g., large, hand-made cigars) are entirely agricultural products composed entirely of tobacco leaf. In asserting jurisdiction over all tobacco products now and in the future, FDA needs account for manufacturers' need to adapt to ever-changing crop conditions. Addressing the newly-deemed tobacco products under FDA's current premarket review scheme will only serve to exacerbate the ongoing disruption to the U.S. tobacco manufacturing industry.

directed FDA to focus its regulations on tobacco products that children and adolescents in fact use. The Congressional findings set forth in the Tobacco Control Act state, among other things, that (i) "the *use* of tobacco products by the Nation's children is a pediatric disease of considerable proportions;" [32] (ii) "virtually all new *users* of tobacco products are under the minimum legal age to purchase such products;"[33] (iii) "advertising, marketing, and promotion of tobacco products have been especially directed to attract young persons...and...have resulted in increased *use* of such products by youth;"[34] (iv) "tobacco advertising and marketing contribute significantly to the *use* of . . . tobacco products by adolescents;"[35] (v) "past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco *use* by adolescents;"[36] and (vi) the federal government has a "substantial interest in reducing the number of children and adolescents who *use*" tobacco products.[37] However, the current premarket review system does not account for the varying risks of youth access and initiation posed by differing tobacco products, thereby frustrating one of the primary purposes of the Tobacco Control Act.

### B. FDA's Proposed Approach to the Deeming Regulation Will Likewise Frustrate the Purposes of the Act

The ongoing failures of the current premarket review process have been and continue to be of critical business concern to SMARTT's members. We are also greatly concerned that the Deeming Regulation, as currently proposed, seems poised to repeat and entrench many of the same problems plaguing the existing regulatory framework.

In the Proposed Rule, FDA once again significantly underestimates the total number of premarket review submissions that the Agency expects to receive for the newly-deemed products. For example, FDA estimates that 343 cigar manufacturers will submit approximately four (4) SE Reports each year for a collective segment total of 1,472 SE Reports each year.[38] However, given the nature of the cigar manufacturing industry and the variety of blends, shapes, and sizes, it is more likely that each cigar manufacturer will itself be required to submit dozens if not hundreds of SE Reports each year. Similarly, FDA estimates that 140 "other tobacco, e-cigarettes, and nicotine product manufacturers" (a category which includes the makers of hookah, dissolvables, e-cigarettes, and all other deemed products except cigars or pipe tobacco) will submit 2.26 SE Reports or PMTAs each year, for a total of 316 such submissions each year.[39] In reality, the number of annual submissions from e-cigarette makers alone is likely to far exceed this sum. Indeed, a recent study reports that "every month since mid-2012, 10 new brands of electronic cigarettes...and more than 240 new flavours have come on the market" and

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32 Tobacco Control Act at § 2(1) (emphasis added).

33 *Id.* at § 2(4).

34 *Id.* at § 2(15).

35 *Id.* at § 2(5).

36 *Id.* at § 2(6).

37 *See id.* at § 2(31).

38 79 Fed. Reg. at 23189.

39 79 Fed. Reg. at 23189.

that "the market for e-cigarettes includes 466 brands and 7,764 unique flavours."[40] Although not specific to the U.S. market, we believe these data are nonetheless indicative of the rapid growth in the e-cigarette segment—and the likelihood that FDA may soon receive thousands of premarket submissions for tobacco products within this category. We would urge FDA to take these and other real-world data into account when estimating the regulatory burden for each deemed product class, rather than simply basing its estimates on FDA's "experience with the existing information collection that applies to . . . currently subject" products, which is neither on point nor relevant in this instance.[41]

Moreover, in addition to underestimating the total number of reports to be expected for newly-deemed products, FDA by its own admission has confirmed that the Agency is not yet in a position to provide meaningful guidance to the industry as to what SE information will ultimately be required. The preamble to the Proposed Rule is replete with acknowledgement that the data on e-cigarettes, dissolvables, and cigars are currently insufficient, and the regulatory science is too unsettled, for the Agency to determine these products' effects on public health at present.[42] Indeed, FDA is actively working to fill this regulatory science vacuum, reportedly spending $270 million to fund 46 research projects to determine the public health risks of e-cigarettes alone.[43] These FDA-funded projects are critical to the Agency's ability to develop appropriate and product category-specific regulations for these products, as they will help answer "basic questions such as what compounds are in the vapour" and "complicated ones like whether flavors such as butterscotch and bubblegum entice children to vape."[44] Researchers have predicted that the results of these e-cigarette studies may not be available until 2018,[45] virtually guaranteeing that any FDA premarket review requirements imposed before this date will be premature and uninformed by regulatory science.

In light of the limitations apparent in the current SE process, SMARTT urges FDA to invest the necessary time and resources to understand the public health profile of each tobacco product class and to tailor premarket review requirements accordingly *prior to requiring industry to make the associated submissions*. Indeed, it is critical for FDA to possess, up-front, an understanding of the available scientific data that are relevant to the public health questions that are bound to arise in industry submissions, so that FDA may proactively tailor the requirements it communicates to industry.[46] As FDA well knows, SE and PMTA submissions

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40 BMJ (formerly British Medical Journal), Market for e-cigarettes includes 466 brands and 7764 unique flavors (Jun. 17, 2014), BMJ 2014;348:g4016.

41 79 Fed. Reg. at 23189.

42 *See, e.g., id.* at 23144.

43 Sharon Begley, *As millions vape, e-cigarette researchers count puffs, scour Facebook*, Reuters, Jul. 10, 2014, http://in.reuters.com/article/2014/07/09/us-health-cigarettes-idINKBN0FE2E320140709.

44 *Id.*

45 *Id.*

46 SMARTT believes that CTP's approach to addressing the potential public health effect of menthol in cigarettes is particularly instructive, and we see no compelling reason or regulatory justification as to why FDA should not take the same approach in the context of the Deeming Regulation. We note that prior to making any decision about what regulatory action, if any, to take regarding menthol, FDA has first sought to evaluate all the available science on the issue. In addition to receiving reports from TPSAC and the

are complex regulatory filings, each one of which requires a substantial amount of industry's financial and human resources to support and prepare, and of FDA resources to review. We do not believe there is any practical or legal justification or need for a premarket regulatory framework which replicates the current process by requiring the submission of several thousands of such documents, followed by the inevitable submissions of several thousands of additional responses to Advice/Information Requests to address purported deficiencies that could have been addressed if FDA had first published guidance that better reflected the regulatory science.

Further, SMARTT is greatly concerned that the Proposed Rule is likely to require the submission of unnecessary SE Reports for product changes which do not implicate the consumed product and, thus, have no impact on public health. The FDCA defines the term ''tobacco product'' to mean ''any product made or derived from tobacco that is intended for human consumption, *including any component, part, or accessory* of a tobacco product...."[47] Nevertheless, the Proposed Rule expressly exempts all "accessories" of deemed products from FDA's tobacco authorities. In explaining the Agency's intended exercise of enforcement discretion in this regard, FDA notes that accessories of proposed deemed products are "items that are not included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product" and, accordingly, are not "expect[ed to] have a significant impact on the public health."[48] Accessories include those items that may be used in the storage or personal possession of a proposed deemed product. Therefore, items such as hookah tongs, bags, cases, charcoal burners and holders, as well as cigar foil cutters, humidors, carriers, and lighters would be considered accessories and would not fall within the scope of the Deeming Regulation.[49] By contrast, "components and parts" of newly-deemed products (including air/smoke filters, tubes, papers, pouches, flavorings, e-cigarette cartridges and other parts that comprise a finished tobacco product or that are intended for consumer use in the consumption of a tobacco product) would be subject to the Act.[50] Although SMARTT certainly supports FDA's regulatory carve-out for tobacco product accessories, we would encourage FDA to extend this same reasoning to the labeling and packaging of a tobacco product—which are likewise "not included as part of a finished tobacco product or intended or expected to be used by consumers in the consumption of a tobacco product"—and should not be reportable for SE purposes, but rather regulated pursuant to CTP's other tobacco authorities (e.g., misbranding provisions).

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industry, FDA independently evaluated the peer- reviewed literature, TPSAC and industry submissions, and other materials, and performed or commissioned additional studies or analyses "in an attempt to fill in and inform some of the gaps in the literature." *See* FDA, Preliminary Scientific Evaluation Of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes, available at http://www.fda.gov/downloads/scienceresearch/specialtopics/peerreviewofscientificinformationandassessments/ucm361598.pdf (last accessed Aug. 6, 2014). We encourage FDA to take a similar approach toward the Deeming Regulation, particularly where the Agency is using tobacco industry user fees to fund Tobacco Centers of Regulatory Science (TCORS) which are presently engaged in research intended to inform the regulation of tobacco products.

47 FDCA § 201(rr)(1), 21 U.S.C. § 321(rr)(1).

48 79 Fed. Reg. at 23153.

49 *Id. at* 23143.

50 *Id.*

In conclusion, SMARTT believes that the current regulatory process for reviewing new tobacco products is badly broken and does not function in a manner consistent with achieving the public health aims of the Act. SMARTT is therefore concerned that FDA appears ready to extend the current one-size-fits-all approach, and its expansive interpretation of the substantial equivalence requirements, to the various unregulated product categories that will soon be swept into the ambit of the FDCA. As FDA well knows, the size and differentiation of the respective deemed product categories (e.g., cigars v. hookah v. pipe tobacco v. e-cigarettes v. dissolvables) demand that FDA's regulatory approach consider the varying usage patterns and youth access issues that are driving the relevant public health outcomes. Toward this end, it is critical that FDA utilize its "new and flexible" enforcement authority to give effect to these products' differing effects on "youth initiation, frequency of use by youth and young adults, and other factors."[51] If FDA is to further the purposes of the Tobacco Control Act and fulfill the stated objectives of the Deeming Regulation, the Agency will have to develop and implement a more nuanced, science-based, and product-specific regulatory framework for tobacco control. SMARTT believes that this new framework should not only draw upon CTP's experience in its first five (5) years of administering the Act, but also the decades of experience of FDA's Center for Device and Radiological Health ("CDRH") which successfully developed a model for the premarket review of medical devices that served as the basis for the analogous premarket provisions of the Tobacco Control Act, and which accounts for a similarly broad spectrum of products and technologies that cannot be appropriately addressed with a one-size-fits-all regulatory model.

## III. FDA SHOULD ESTABLISH A CATEGORY-SPECIFIC FRAMEWORK FOR PREMARKET REVIEW OF TOBACCO PRODUCTS

While not acknowledging the flaws in the current premarket review process, the Proposed Rule signals FDA's willingness to consider more appropriate and less burdensome alternatives for certain categories of tobacco products. Among other things, the Proposed Rule acknowledges that many newly-deemed tobacco products will be unable to utilize the substantial equivalence pathway due to the lack of a "grandfathered" predicate tobacco product.[52] FDA has also recognized that different categories of deemed tobacco products may have the potential for varying levels of harm and negative effects on public health.[53] FDA therefore seeks comment on alternative marketing pathways or policy options for those newly-deemed products unable to utilize the substantial equivalence pathway, and/or alternate interpretations of the substantial equivalence provisions that would allow manufacturers to utilize this pathway even in the absence of a clear predicate.

In response, SMARTT notes that, in lieu of requiring each manufacturer of a deemed tobacco product to submit a "full" Premarket Tobacco Product Application ("PMTA") in order to continue marketing its product, CTP has the flexibility under the Tobacco Control Act to promulgate and implement a tobacco product category-specific premarket review structure that will allow the Agency to meet the public health goals of the statute while avoiding unnecessary

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51 *Id.* at 23150.

52 *See id.* at 23174.

53 *Id.* at 23177.

disruption to the industry. In this Section, we summarize the legal and regulatory bases for such a category-specific approach.

### A. A Different Compliance Policy Is Necessary To Achieve The Purposes of the Tobacco Control Act

FDA's proposed compliance policy would require manufacturers to submit SE Reports or PMTAs prior to the end of the 24-month period following the effective date of the Deeming Regulation.[54] Based on the circumstances surrounding implementation of Sections 910 and 905(j) of the Tobacco Control Act to date, we believe effectuation of this policy would unnecessarily burden CTP's limited resources and result in a significant disruption to industry.

As discussed above in Section II.B., FDA expects that the compliance policy set forth in the Draft Regulation will result, at minimum in the submission of more than a thousand SE Reports. Moreover, the SE pathway is an option only for those newly-deemed products which can identify an acceptable predicate product. Under the proposed framework, those products for which there is no predicate would require the submission of PMTAs. While the PMTA pathway has been available to tobacco product manufacturers since the effective date of the Tobacco Control Act, only four (4) PMTAs have been submitted to date and not a single one of those has been accepted for filing by CTP.[55] We believe the relative dearth of PMTA submissions is due primarily to two factors. First, based on CTP's draft guidance on PMTAs (the "PMTA Guidance"),[56] a manufacturer may reasonably conclude that any such submission—regardless of the risk profile of the tobacco product at issue—must be supported by well-controlled clinical studies that are organized and conducted like late-stage clinical studies on new drug and medical device products. Completing the studies recommended in the PMTA Guidance would likely require the investment of millions of dollars and take many years to achieve. Second, the regulatory standard against which these studies are conducted is new and untested, and CTP has never applied it in practice. Unlike a late-stage clinical study on a drug, which is based on defined efficacy endpoints for the disease or condition at issue, clinical studies on tobacco products must be conducted against the ambiguous "appropriate for the protection of public health" standard set forth in the Tobacco Control Act. While the PMTA Guidance provides some clarification on CTP's expectations for such studies and its interpretation of the "appropriate for the protection of the public health" standard, the small number of PMTA submissions made over the past five (5) years reflects a reasonable determination by the regulated industry that the PMTA pathway will require significant time and expense with an inherently uncertain outcome.

These factors further indicate that the current PMTA Guidance and the data requirements set forth therein would be the worst possible vehicle for "catch-up" PMTAs

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54 *Id.* at 23175.

55 *See* http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm (last accessed August 1, 2014).

56 *See* Draft Guidance for Industry: Applications for Premarket Review of New Tobacco Products, Sept. 2011, available at http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM273425.pdf.

covering products for which there are no pre-2007 "grandfathered" predicates available. The process for regulating tobacco products has obvious similarities to the process for regulating medical devices. Like the premarket framework for tobacco products, the medical device framework has a substantial equivalence process established pursuant to Section 510(k) of the FDCA which is available to new medical devices for which a legally marketed predicate device is available.[57] Those new devices for which there is no legally marketed predicate are subject to the premarket approval (PMA) process.[58] Like PMAs for new medical devices, PMTAs are clearly intended to apply to tobacco products that are truly novel and present different questions of public health. In both cases, this novelty gives rise to a resource-intensive review by the Agency, and for tobacco products in particular, the involvement and review of the Tobacco Products Scientific Advisory Committee ("TPSAC").[59] As discussed in Section II.B., we believe that the compliance policy set forth in the Proposed Rule will result in the submission of thousands of PMTAs for electronic cigarettes and other tobacco products for which there is no clear predicate product. We also believe that, based on CTP's past experience in applying the premarket requirements to the currently regulated categories of tobacco products, CTP lacks the resources to (i) honor the PMTA Guidance and, during the currently-proposed 24-month grace period, work with industry in designing and implementing the required clinical studies for each of the several thousand expected PMTAs; and (ii) review such a deluge of PMTAs within 180 days of filing, as required by statute.[60] Thus, CTP must find another way to review these products while complying with its statutory mandate.

### B. The Tobacco Control Act Vests FDA With Flexibility and Discretion in Applying the Premarket Review Provisions

CTP acknowledges these problems in the preamble to the Proposed Rule and has solicited comment on "whether there are ways that we might provide additional flexibility with respect to PMTAs that would still be appropriately protective for the public health."[61] CTP asks whether there are "alternative marketing pathways or policy options" that could apply to tobacco products without predicates as of February 15, 2007, and notes that there may be cases in which an "applicant may not need to conduct any new nonclinical or clinical studies" given a pre-existing understanding of the products health impacts and/or the fact that the product may contain substantially lower levels of toxicants.[62] Finally, CTP asks whether there are other "legal interpretations of the substantial equivalence grandfather provision that FDA should consider."[63]

SMARTT believes there are alternatives that would allow CTP to invest its limited resources in scrutinizing tobacco products according to CTP's stated position that

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57 FDCA § 510(k); 21 U.S.C. § 360(k).

58 FDCA § 515; 21 U.S.C. § 360e.

59 FDCA § 910(b)(2); 21 U.S.C. § 387j(b)(2).

60 FDCA § 910(c)(1); 21 U.S.C. § 387j(c)(1).

61 79 Fed. Reg. at 23175.

62 *Id.* at 23176.

63 *Id.*

different tobacco product present different hazards. These alternatives are based on a reasonable legal interpretation of both the SE and PMTA provisions in the Tobacco Control Act that provides CTP with significant flexibility in applying these premarket review provisions.

- *Substantial Equivalence*. The definition of substantial equivalence set forth in the Tobacco Control Act provides FDA with discretion to review newly-deemed products, including novel products with no apparent predicates, by comparing them to traditionally marketed tobacco products. Specifically, the statute (i) permits a manufacturer to submit an SE Report for a tobacco product that has "different characteristics" than a predicate tobacco product and (ii) allows CTP to issue an order of substantial equivalence if the product "does not raise different questions of public health."[64] Based on this definition, a manufacturer may submit an SE Report for a tobacco product possessing distinct characteristics (as compared to currently marketed products), and FDA may issue an SE Order if it determines that the product does not raise different questions of public health. Although this interpretation would require CTP to deviate from its current approach to the SE provision (which essentially requires equivalence in characteristics), the Tobacco Control Act contemplates an alternative approach and expressly permits tobacco product manufacturers to utilize the SE process in this manner. Indeed, this statutorily-permissible and flexible interpretation would permit CTP to review newly deemed products in a more efficient and less burdensome manner.

- *PMTAs*. The text of Section 910 of the Act provides CTP with similar flexibility to regulate tobacco products in a manner that accounts for the particular features and hazards of the product at issue. In particular, the statute requires well-controlled clinical studies in support of a PMTA only "when appropriate," and explicitly authorizes CTP to rely on other "valid scientific evidence" when such evidence is sufficient to evaluate the tobacco product.[65] There is no analogous qualification in the FDCA's premarket approval requirements for medical devices,[66] which mirrors Section 910 in all other material respects. Thus, unlike PMA approval for medical devices, the Tobacco Control Act clearly contemplates that PMTAs for new tobacco products will not be subject to a one-size-fits-all approach. Instead, it urges CTP to implement differing PMTA requirements depending on the product at issue.

In sum, CTP is not shackled to the binary choice of an SE Report or a PMTA supported by clinical investigations. Rather, based on the text of the statute, CTP is authorized to implement a wide range of product-specific compliance policies, one of which we detail below.

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64 FDCA § 910(a)(3)(A)(ii); 21 U.S.C. § 387j(a)(3)(A)(ii). "Characteristics" refers to features such as, among others, materials, ingredients, design, composition, and heating source. *Id.*

65 FDCA § 910(c)(5); 21 U.S.C. § 387j(c)(5).

66 *See* FDCA § 515; 21 U.S.C. § 360e.

### 1. FDA Should Develop A Compliance Policy for Each Tobacco Class Based on the Use of General and "Special" Controls

As the preamble to the Deeming Regulation notes, the Proposed Rule would subject newly-deemed covered tobacco products to the "general controls" set forth in the FDCA, including:

- *Prohibition on adulteration and misbranding*. According to CTP, this prohibition will ensure that "every tobacco product meets the same basic requirements and ensure that the labeling of such products is not false or misleading. FDA would be able to take enforcement action against any tobacco products that did not meet these basic standards."[67]

- *Ingredient listing and reporting of Harmful and Potentially Harmful Constituents ("HPHCs")*. CTP notes that this requirement will "assist FDA in better understanding the contents of regulated products and their health consequences...and determining if future regulations to address the health risks posed by particular products are warranted."[68]

- *Registration and Product Listing*. CTP states that this "critical information" would facilitate efficient inspections of tobacco product manufacturing facilities and the initiation of enforcement when warranted.[69]

- *Prohibition on Modified Risk Claims*. Manufacturers will be prevented from utilizing modified risk claims on labeling without the issuance of an order under Section 911, which will "help reduce consumer confusion" and potentially lead to increased cessation and reduced initiation.[70]

- *Submission of Research and Health Effects Data*. Under Section 904(a), a manufacturer of a newly-deemed tobacco product will be required to submit all documents developed after the effective date that relate to the health, toxicological, behavioral, or physiologic effects of the tobacco product, and, under Section 904(b), CTP may also request that manufacturers provide historical documentation on these issues.

These general controls provide CTP with ample authority to regulate newly-deemed covered tobacco products and to take enforcement action against those products that are in violation of the Act. In addition, they ensure that CTP will receive a large amount of information on the health profiles of these newly deemed products by the time manufacturers would otherwise be required to make premarket submissions under Section 910 of the Act. In fact, the authority provided by the general controls, together with the information that manufacturers will submit pursuant to these requirements, will permit CTP to prepare tobacco-class specific premarket guidance in lieu of the current compliance policy, which would

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67 79 Fed. Reg. at 23148.

68 *Id.*

69 *Id.* at 23149.

70 *Id.*

otherwise result in the submission of thousands of PMTAs and SE Reports that FDA would be required to review in isolation and on an individual basis in accordance with any applicable timelines established by the Tobacco Control Act.

Such class-specific guidance could be developed according to a framework similar to that which CDRH uses to prepare guidance documents for medical devices reviewed via the *de novo* process.[71] The *de novo* process is a framework for reviewing new medical devices for which no predicate exists. These devices are "automatically" classified into the most stringent regulatory category (Class III), thus requiring submission of a Premarket Approval Application ("PMA") supported by clinical data.[72] The *de novo* process permits the reclassification of lower risk devices based on non-clinical data and "special controls" intended to address the risks posed by that particular device and, subsequently, other devices within that classification.[73] In particular, the *de novo* process permits FDA to reclassify (into Class II) "devices for which general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance."[74] Such special controls are generally specific to the type of device and may include performance standards, postmarket surveillance requirements, special labeling requirements, and premarket data requirements, among other things.[75]

The medical device *de novo* process was established by Congress in amendments[76] to the FDCA intended to address much the same problem currently confronted by CTP—namely, the potential waste of industry and FDA resources associated with a "full" PMA process where other measures are sufficient. As FDA noted in discussing the *de novo* process, "Congress included this section to limit unnecessary expenditure of CDRH and manufacturer resources that could occur if low risk devices were subject to premarket approval (PMA)...."[77] However, unlike the medical device framework, which requires that approval of a PMA be based on clinical data,[78] the Tobacco Control Act *immediately granted* CTP the authority to implement a similar framework without the need for Congressional intervention. As noted above, FDCA Section 910 expressly permits CTP to rely on any "valid scientific evidence" in lieu of full reports of well-controlled clinical investigations in approving a PMTA. Moreover, as a complement to these PMTA authorities, CTP also has the authority to issue SE Orders to tobacco

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71 *See* FDCA § 513(f)(2); 21 U.S.C. § 360c(f)(2).

72 *See* FDCA § 513(f)(1); 21 U.S.C. § 360c(f)(1).

73 *See* FDCA § 513(f)(2); 21 U.S.C. § 360c(f)(2).

74 *See* FDA, Regulatory Controls: Special Controls, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm#special.

75 *See id.*

76 This flexibility was not originally provided in the analogous medical device provisions of the Act, but rather was granted by Congress in enacting the *de novo* provisions in the Food and Drug Administration Modernization Act of 1997, P.L. 105-115 (Nov. 27, 1997).

77 *See* Guidance for Industry and FDA Staff, "New Section 513(f)(2) – Evaluation of Automatic Class III Designation" (February 19, 1998).

78 *See* FDCA § 515(c); 21 U.S.C. § 360e(c).

products that have different characteristics than their predicates, but that do not raise different questions of public health.[79]

SMARTT believes that the text of the Tobacco Control Act and CTP's general authority over tobacco products provides the Agency with two fundamentally different approaches to constructing a premarket compliance policy. On the one hand, under the policy described in the Proposed Rule, CTP could provide a blanket 24-month compliance period for submissions of SE Reports and PMTAs for the newly-deemed tobacco products, and then face the prospect of receiving thousands of premarket reports that must be reviewed individually and, in the case of PMTAs, under a statutorily-mandated review clock of 180 days.[80] Based on CTP's experience in receiving and reviewing premarket reports to date, we respectfully submit that this policy would result in significant market disruption, a waste of industry and CTP resources, the receipt of "incomplete" submissions requiring redress as FDA's understanding of the newly-deemed tobacco products evolves, and other unintended and (as yet) unforeseeable consequences.

Alternatively, CTP could avoid these consequences by crafting a compliance policy that establishes targeted, up-front, category-specific guidance for tobacco product manufacturers on the requirements for premarket review. In promulgating such guidance, CTP should do all the following:

- Base the compliance period not on the effective date of the final regulation, but rather the issuance of a regulation or guidance setting forth the premarket requirements for a particular class of deemed tobacco product (e.g., electronic cigarettes, cigars, pipe, hookah, etc.). At minimum, the compliance period should be 48, not 24, months due to FDA's current knowledge deficit and the likelihood that new tests and equipment will need to be developed and validated for use by industry in the interim.

- Review the information provided by industry to this docket, and the health information to be supplied by tobacco product manufacturers under FDCA Sections 904 and 905 of the Tobacco Control Act within approximately six months of the effective date of the Deeming Regulation. This will include, among other information:

  - listing of all SKUs for newly-deemed tobacco products, which will provide CTP with a preview of the likely number of premarket submissions that will be filed under Section 910;

  - listing of all ingredients and additives by brand and subbrand; and

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79 FDCA § 910(a)(3); 21 U.S.C. § 387j(a)(3).

80 FDCA § 910(c)(1)(A); 21 U.S.C. § 387j(c)(1)(A).

- documentation related to research on the health, toxicological, behavioral, or physiologic effects of the newly-deemed tobacco products.

- Upon examination of this information, prioritize the development of category-specific premarket review guidance.

- For each class of tobacco product, issue draft guidance establishing the requirements for premarket review, including the "special controls" to be imposed on that class of product. The draft guidance could also include additional category-specific requirements for:

  - tobacco product standards (e.g., the use of characterizing flavors);

  - advertising and promotional requirements; and

  - good manufacturing practices.

For example, in a premarket guidance document for electronic cigarettes, CTP could establish a special control requiring additional nonclinical or clinical data in connection with the use of flavors. Further, the guidance document could establish performance standards (akin to device standards) for electronic cigarettes based on the information obtained by CTP under the Act. Ultimately, while the form of application for electronic cigarettes or other novel products would be a PMTA (assuming the lack of a pre-2007 predicate) the premarket guidance document would essentially establish a premarket process that would permit comparisons to a "reference predicate" in connection with FDA's assessment of whether approval of the product is appropriate for the protection of the public health.

We believe this recommended compliance policy is a significant improvement over that set forth in the Proposed Rule and will be enabling for both CTP and the industry. First, it will allow CTP to establish discrete premarket review requirements for each category of tobacco products, based upon the product-specific scientific knowledge base that CTP will possess upon review of the information provided to this docket and by newly-regulated manufacturers under Sections 904 and 905 upon the effective date of the regulation. In particular, CTP will be positioned to specify, in the form of "special controls," the nonclinical and, where appropriate, clinical data requirements for premarket submissions for each category of tobacco product, and even within the category itself.

Additionally, this would, in turn, provide industry with foreknowledge of the requirements for their submissions, improving the quality and sufficiency of PMTAs and SE Reports and allowing CTP to avoid the need to schedule and conduct the hundreds of pre-submission meetings that would likely be requested if CTP were to apply the premarket requirements as outlined in its proposed compliance policy. Finally, this recommended compliance policy would allow CTP stagger the issuance of guidance documents and associated dates for submissions of premarket reports, thus avoiding the deluge of submissions (spanning a host of product classes) that is sure to occur if CTP moves forward with the current proposal.

Finally, it bears emphasis that our suggested compliance policy does not undermine the public health goals of the Act. CTP itself has indicated a willingness to increase the compliance period for certain categories of tobacco products, and to limit the data requirements applied to others, where warranted and appropriate for the protection of the public health.[81] The compliance policy described herein provides a means to do so in a manner that is consistent with both the text and purposes of the Act. Just as important, implementation of this policy will streamline reviews and allow CTP to direct its resources toward those categories of deemed tobacco products that present a greater risk to public health. Finally, as described above, CTP will retain at all times ample authority to take enforcement action against those products that present an undue risk to health and/or are in violation of the Act.

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We thank you in advance for your consideration of our recommendations, and appreciate this opportunity to share our perspectives with the Agency. We look forward to continuing to assist FDA in its efforts to protect the public health through reasonable regulation devoid of unnecessary burdens on either the Agency or regulated industry.

Respectfully,

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81 79 Fed. Reg. at 23177.

## Blue Door Vaping - Statistics

- Began as a part time business June 1, 2013 in Mechanicsburg PA (under 100 SKUs)
  - Sales for 2013 = $75,614
  - Sales tax paid in 2013 = $4,536
  - Payroll paid out in 2013 = $10,164.91
  - Payroll taxes paid in 2013 by employees = $1,987.63
  - Payroll taxes and benefits paid in 2013 by employer = $2,359.58
- Opened 2nd location in January 2014 (Over 400 SKUs)
  - Sales for 2014 = $508,070
  - Sales tax paid in 2014 = $30,484
  - Payroll paid out in 2014 = $154,493.37
  - Payroll taxes paid in 2014 by employees = $31,207.06
  - Payroll taxes and benefits paid in 2014 by employer = $34,558.94
- Opened 3rd location in January 2015 (Over 750 SKUs)
  - YTD sales for 2015 (as of 11/30/15) = $541,433
  - YTD sales tax paid in 2015 = $32,485
  - YTD Payroll paid out in 2015 = $199,820.78
  - YTD payroll Taxes paid in 2015 by employees = $43,058.30
  - YTD payroll taxes and benefits paid in 2015 by employer = $42,327.34

Since Inception (30 Months)

- Sales since inception (as of 11/30/15) = $1,125,117.00
- Sales tax paid since inception = $67,505
- Payroll paid out since inception = $364,479.06
- Payroll Taxes paid since inception by employees = $76,252.99
- Payroll taxes and benefits paid by employer since inception 2015 = $79,245.86

Currently employ 8 employees with a weekly payroll of approximately $4,000

Current customer count <6500 customers

Currently 978 SKUs in our POS system

Based on the FDA estimate of the cost of PMTA (which is likely dramatically understated) these SKUs would cost $326,215,812.00 and require over 4,890,000 man hours of labor to submit applications for approval with NO guarantee of approval

The deeming regulation as proposed would close my three stores and layoff 8 employees

According to Executive Order #13563 The Office of Management and Budget is tasked with the following. I do not believe that the FDA has fully met the requirements of this executive order with their proposed deeming regulation for electronic cigarettes and vapor products.

Section 1 – General Principles of Regulation

***(a)Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It must be based on the best available science.***

The FDA has seemingly ignored much of the available science when deciding to regulate electronic cigarettes and vapor products in the same way as tobacco products. Vapor products have a huge potential to be used as a harm reduction tool as exhibited by the following pieces of scientific information:

- While it is known that combustible tobacco cigarettes pose harm to users through secondhand smoke, the same is not true with vapor products as shown in the IVAQS study completed in 2012. ***Attached Section 1***
- A study title 'Peering through the Mist: What does the chemistry of contaminants in electronic cigarettes tell us about health risks?, conducted by Dr. Igor Burstyn from Drexel University School of Public Health ***Attached Section 2*** concludes that:
    - the exposures from using e-cigarettes fall well below the threshold for concern for compounds with known toxicity
    - There is no serious concern about the contaminants such as volatile organic compounds (formaldehyde, acrolein, etc.) in the liquid or produced by heating.
- **Safety evaluation and risk assessment of electronic cigarettes as tobacco substitutes.** 2014 Dr. Konstantinos Farsalinos MD, Onasis Cardiac Surgery Center, Greece ***Attached Section 3*** concludes that:
    - Currently available evidence indicates that electronic cigarettes are by far a less harmful alternative to smoking and significant health benefits are expected in smokers who switch from tobacco to electronic cigarettes.
- **Characteristics, Perceived Side Effects and Benefits of Electronic Cigarette Use.** 2014 Online survey of over 19,000 consumers - Dr. Konstantinos Farsalinos MD et al, Onasis Cardiac Surgery Center, Greece ***Attached Section 4*** concludes:
    - 'It seems that ECs are used as long-term substitutes to smoking. They can be effective even in subjects who are highly dependent on smoking and are heavy smokers.'
- **Impact of Flavour Variability on Electronc Cigarette Use Experience.** 2013 Dr. Konstantinos Farsalinos MD et al, Onasis Cardiac Surgery Center, Greece ***Attached Section 5*** concludes:
    - EC liquid flavourings play a major role in the overall experience of dedicated users and support the hypothesis that they are important contributors in reducing or eliminating smoking consumption.
- A recently published study by Public Health England ***Attached Section 6*** concludes:
    - E-cigarettes have the potential to help smokers quit
    - E-cigarettes are around 95% less harmful than smoking
    - There is no evidence so far that e-cigarettes are acting as a route into smoking for children or non-smokers

***(a)It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends.***

- Instead of considering electronic cigarettes and vapor products as a new and innovative technology advancement that has value as a harm reduction tool, the FDA has decided to treat them the same as previous combustible tobacco products. This regulatory framework is onerous, expensive, time consuming, and burdensome for an industry that is primarily populated by small and micro businesses. The FDA should consider an alternative framework for approval of these reduced harm products.

***(a)It must take into account benefits and costs, both quantitative and qualitative and propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs***

Benefits

- When discussing the direct benefits of deeming electronic cigarettes tobacco products, the FDA stated *"The direct benefits of making each of the proposed deemed tobacco products subject to the requirements of chapter IX of the FD&C Act are difficult to quantify without additional data, and we cannot predict the size of these benefits at this time."*

Potential cost of regulation

Both the financial and public health costs of adoption of this regulation will be tremendous.

- FDA's own estimates are that the regulatory process will remove 98.5% of all vapor products from the market. Wells Fargo analyst Bonnie Herzog estimates that the e-cigarette and vapor product market to reach $3.5 billion in 2015. ***Attached Section 7** Removing 98.5% of those products would result in an overall industry loss of $3.44 billion in revenue to the US economy.
- E-cigarette and vapor products are poised to save the Medicaid system billions of dollars in reduced healthcare costs. ***Attached Section 8***
    - Based on the findings of a rigorous and comprehensive study on the impact of cigarette smoking on Medicaid spending, the potential savings of e-cig adoption, and the resulting tobacco smoking cessation and harm reduction, could have been up to $48 billion in Fiscal Year (FY) 2012.2 This savings is 87% higher than all state cigarette tax collections and tobacco settlement collections ($24.4 billion) collected in that same year.
    - The deeming regulation as proposed will negate approximately $50,000,000,000 per year in potential Medicaid savings.
- No information was presented by the FDA as to the estimated number of business that would be affected (closed) by this regulation. It is estimated that as of January 2014, there are between 6,000 and 7,000 'Vape Shops' (retail locations selling strictly vapor products) in the US. Most are small or micro businesses employing less than 10 people. Even if we apply an average of 3 employees per Vape Shop, the lack of availability of these products will likely cause the unemployment of over 18,000 people.

## What would I pose as alternatives to the existing proposed regulations?

1. **Alter the grandfather date for products required to receive approvals.**
    a. My shops do not currently sell (and never has sold) a single product that was on the market (or is substantially equivalent to a product that was on the market) in February of 2007.
    b. Propose allowing all products on the market as of the release date of the final regulation to be permitted to stay on the market without the need for PMTA or Substantial Equivalency application process.
        i. While this would stifle innovation going forward, it would likely allow my business and many like it to remain in business and continue to employee people.
2. **Create a new category entirely for these products rather than labeling them a Tobacco product.(based on the Self-executing provisions of the Tobacco Control Act) and by doing so, enact meaningful regulations on the safety of the product itself.**
    a. Execute their enforcement authority against products determined to be adulterated and misbranded.
    b. Provision and enforcement of good manufacturing practices (GMP), if appropriately tailored to address manufacturing of e-cigarettes and distinct from manufacturing of tobacco products.
    c. Requiring submission of ingredient listing and reporting of harmful constituents
    d. Requiring registration and product listing for all e-cigarette products
    e. National age to purchase vapor products of 18+.
    f. Requirement of child resistant packaging for e-liquid products that contain nicotine
    g. These products are NOT tobacco products, but technology products. Traditional tobacco cigarette smokers DO NOT die from the nicotine (which has been proven to have many positive benefits), but they die from the inhalation of smoke associated with tobacco cigarettes. These products (as shown by many scientific studies) deliver nicotine in a reduced harm manner.
3. **Streamline both the PMTA and Substantial equivalency process to allow for continued innovation.**
    a. Innovation within this industry is largely responsible for allowing more and more current smokers to find a satisfying alternative to smoking combustible tobacco cigarettes.
        i. As a retailer there are, on average, 5-8 new products PER WEEK offered to me by manufacturers as new and innovated vs. products currently on the market.
    b. Allow the population level health question to be answered by in-depth studies conducted by the FDA rather than requiring this as part of the PMTA or substantial equivalency application process.
    c. Allow the ingredients/components to submit applications for approval rather than the final finished product.
    d. Allow for applications from different companies to use the data gathered from previous applications within their applications rather than requiring a duplication of this work.

CONCLUSION: Millions of former smokers have found a solution for an age old problem through our free market system. We as consumers have found a reduced harm alternative to smoking combustible tobacco cigarettes. As a retailer, I have found customers are enthralled and empowered with this idea which is why I have seen such rapid growth in sales in my business. The deeming regulation in its current proposed format would not only eliminate thousands of jobs and billions of dollars in economic benefits, but would force the over 9 million current vapers in the U.S. to either return to smoking tobacco cigarettes or attempt to circumvent the laws by finding underground or black market sources for these products.

The mission statement of the FDA states they are responsible for protecting the public health by assuring product safety and advancing public health by speeding innovations through accurate, science-based information. They have failed on all accounts with this proposed regulation by virtually guaranteeing the removal of a reduced harm alternative to tobacco cigarettes which many educated Public Health officials have labeled "The greatest innovation in health since the invention of penicillin".